## THE CLAIMS

1. (original) A method for treating the disease state in mammals caused by mammalian nasal and sinus cells involved in the inflammatory response comprising: contacting the mammalian nasal and sinus cells with an inflammatory mediator; wherein the inflammatory mediator is present in an amount capable of reducing the undesired inflammatory response and is an antioxidant.

2. (original) The method according to claim 1, wherein the inflammatory mediator is formulated into nasal drops.

3. (original) The method according to claim 2, wherein the inflammatory mediator is formulated in a concentration of about 0.1mM to 10.0 mM.

4. (original) The method according to claim 1, wherein the inflammatory mediator is formulated into a nasal ointment.

5. (original) The method according to claim 4, wherein the inflammatory mediator is formulated in a concentration of 0.1mM to 10.0 mM.

6. (original) The method of claim 1 wherein the inflammatory response being reduced is at least one of the following: oxygen radical production, hydrogen peroxide production, cytokine and protease production, prostaglandin production, erythema, histamine and interleukin production.

7. (original) The method of claim 1 wherein the inflammatory mediator is at least one compound selected from the group consisting of: a pyruvate precursor, pyruvate, and mixtures thereof.

8. (original) The method of claim 7 wherein the inflammatory mediator is pyruvate.

9. (original) The method of claim 7 wherein the pyruvate is selected from the group consisting of pyruvic acid, lithium pyruvate, sodium pyruvate, potassium pyruvate, magnesium pyruvate, calcium pyruvate, zinc pyruvate, manganese pyruvate, and mixtures thereof.

A1 cont'd

10. (original) The method of claim 7 wherein the inflammatory mediator is a pyruvate precursor.

11. (original) The method of claim 10 wherein the pyruvate precursor is selected from the group consisting of pyruvyl-glycene, pyruvyl-alanine, pyruvyl-leucine, pyruval cysteine, pyruvyl-valine, pyruvyl-isoleucine, pyruvyl-phenylalanine, pyruvamide, dihydroxyacetone, propylene glycol and salts of pyruvic acid.

12. (original) The method of claim 1 wherein the disease state is selected from the group consisting of rhinitis, eosiophilia syndrome, and sinusitis.

13. (original) The method of claim 1 further comprising contacting the mammalian nasal and sinus cells with a therapeutic agent.

14. (original) The method of claim 13 wherein the therapeutic agent is administered prior to the inflammatory mediator.

15. (original) The method of claim 13 wherein the therapeutic agent is administered concomitantly with administration of the inflammatory mediator.

A1 cont'd

16. (original) The method of claim 13 wherein the therapeutic agent is administered after administration of the inflammatory mediator.

17. (original) The method of claim 13 wherein the therapeutic agent is one or more agents selected from the group consisting of antibacterials, antivirals, antifungals, antihistamines, proteins, enzymes, hormones, nonsteroidal anti-inflammatories, cytokines, insulin, vitamins and steroids.

18. (original) The method of claim 13 wherein the therapeutic agent is oxymetazoline.

19. (original) A nasal solution, comprising:

a) water,

b) sodium chloride, 0.65% by weight,

c) pyruvate, at least 0.1mM,

d) buffer, and optionally

e) a preservative.

wherein the nasal moisturizing saline solution is buffered and made isotonic.

20. (original) The nasal solution of claim 19, wherein the pyruvate is present in the solution at a concentration between from about 0.1mM to about 10mM.

21. (original) The nasal solution of claim 19, wherein the pyruvate is present in the solution at a concentration between from about 0.5mM to about 10mM.

A1 contd

22. (original) The nasal solution of claim 19, wherein the buffer is selected from the group consisting of sodium bicarbonate, disodium phosphate/sodium phosphate, and monobasic potassium phosphate/sodium hydroxide.

23. (original) The nasal solution of claim 19, wherein the preservative is selected from the group consisting of phenylcarbinol, benzalkonium chloride, and thimerosal.

24. (original) The nasal solution of claim 19, wherein the pyruvate is present in the solution at a concentration of about 5mM, the buffer is sodium bicarbonate.

25. (original) The nasal solution of claim 19 further comprising a therapeutic agent wherein the therapeutic agent is one or more agents selected from the group

consisting of antibacterials, antivirals, antifungals, antihistamines, proteins, enzymes, hormones, nonsteroidal anti-inflammatories, cytokines, insulin, vitamins and steroids.

26. (original) The method of claim 13 wherein the therapeutic agent is oxymetazoline.

27. (original) A method for the prevention and/or treatment of rhinitis, eosinophilia syndrome, sinusitis and related conditions associated with nasal congestion, comprising administering a nasal solution to the nostrils of a patient in need thereof, wherein the nasal moisturizing saline solution comprises:

a) water,

b) sodium chloride, 0.65% by weight,

c) pyruvate, at least 0.1mM,

d) buffer, and optionally

e) a preservative.

wherein the nasal moisturizing saline solution is buffered and made isotonic.

A1 cont'd

28. (original) The method of claim 27, wherein the pyruvate is present in the solution at a concentration between from about 0.1mM to about 10mM.

29. (original) The method of claim 27, wherein the buffer is selected from the group consisting of sodium bicarbonate, disodium phosphate/sodium phosphate, and monobasic potassium phosphate/sodium hydroxide.

**RESPONSE**

The Examiner has required restriction of the claims to one of the following inventions under 35 U.S.C. Section 121.

Claims 1-18, 26-30, drawn to a method of treating nasal and sinus diseases employing an inflammatory mediator and a therapeutic agent, classified in class 514, subclass 1+.

Claims 19-25, drawn to a nasal solution composition, classified in class 514, subclass 625.

The Examiner states that inventions I and II are related as product and process of use and the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. In the instant case, the Examiner states that sinusitis can be treated employing a materially different product, i.e., oral antibiotics; similarly rhinitis can be treated by mast cell stabilizers. The Examiner states that because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The Examiner states that claims 1-30 are generic to a plurality of disclosed patentably distinct species comprising therapeutic agents, e.g., inflammatory mediators, antivirals, antifungals, antihistamines, proteins, enzymes, hormones, NSAIDS, etc. The Examiner has required applicant to elect a single disclosed

species, even though this requirement is traversed. The Examiner maintains that each therapeutic category has many members classified in many different subclasses of class 514 and the search for each and every therapeutic category is therefore an undue burden on the office. The Examiner has required applicant to elect a particular inflammatory mediator and a particular therapeutic agent for examination purposes.

The Examiner maintains that the species contained in these claims are so unrelated and diverse that a reference anticipating one of the species would not anticipate or render obvious the other species. Furthermore, the Examiner argues that a search for all the species set forth in each of these claims is an undue burden for the office. The Examiner advises applicant that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of claims readable thereon.

Applicants elect to prosecute the claims of Group 1, claims 1-18 and 26-30, drawn to a method of treating nasal and sinus diseases employing an inflammatory mediator and a therapeutic agent. Applicant elects pyruvate and pyruvate precursors as the particular inflammatory mediator (original claim 7) and antibacterials as the particular therapeutic agent (new claim 31) for examination purposes. Applicant has added new claim 31 to recite antibacterials as the particular therapeutic agent. Claims 1-16 and 26-31 are currently readable on applicants' pyruvate and pyruvate precursors inflammatory mediator and antibacterial therapeutic agent. Applicants traverse the Examiner's restriction requirements.

A restriction requirement is proper if a product and a method of using the product can be shown to be distinct inventions. The product and the method of using the product are distinct inventions if (1) the method as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different method, M.P.E.P. 806.05(h).

M.P.E.P. Section 803 states that there are two criteria for a proper requirement for restriction between patentably distinct inventions:

(1) The inventions must be independent ... or distinct as claimed; and

(2) There must be a serious burden on the Examiner if restriction is not required...(emphasis added, citations omitted).

If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions, M.P.E.P. Section 803. Applicants contend that the search and examination of the present application can be made without serious burden and request the Examiner to examine it on the merits.

Hence, applicants' product claims and method claims for using the product are not distinct inventions and restriction is not proper. In view of the foregoing Response, applicants request reconsideration pursuant to 37 C.F.R. Section 1.143 of the Examiner's position requiring restriction so that all of the claims can be examined in this single application thus helping to expedite prosecution of this application.

Applicants request the Examiner to telephone the undersigned attorney should the Examiner have any questions or comments which might be most expeditiously handled by a telephone conference. Applicants' attorney authorizes

the Examiner to charge Deposit Account 13-4822 if there are any additional charges in connection with this Response.

Respectfully submitted,
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